PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03514.115	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/34511	International filing date *(day/month/year)* 30 October 2003 (30.10.2003)	Priority date *(day/month/year)* 30 October 2002 (30.10.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/00 and US Cl.: 514/12		
Applicant THE UNITED STATES OF AMERICA AS REPRESENTED BY THE SECRETARY OF HEALTH AND HUMAN SERVIES,		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10 May 2004 (10.05.2004)	24 June 2004 (24.06.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 872-9306	Authorized officer B. Dell Chism F. Roberts for Telephone No. (571) 272-1600

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/34511

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description:
pages 1-114 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages 119-121, filed with the letter of 10 May 2004 (10.05.2004)

☒ the drawings:
pages 1-16, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the sequence listing part of the description:
pages 1-4, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in printed form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/34511

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-26	YES
	Claims NONE	NO
Inventive Step (IS)	Claims 1-26	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims 1-26	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest methods of treating sepsis, inflammation or infection comprising administering pharmaceuticals that target SR-BI/CLA-1.

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

What Is Claimed Is:

Claim 1. A method for the treatment of sepsis, inflammation or infection comprising providing to a recipient a physiologically effective amount of a pharmaceutical composition comprising a molecule that targets SR-BI/CLA-1.

Claim 2. The method of claim 1, wherein said method provides a treatment for sepsis.

Claim 3. The method of claim 1, wherein said method provides a treatment for inflammation.

Claim 4. The method of claim 1, wherein said method provides a treatment for infection.

Claim 5. The method of claim 1, wherein said molecule is a peptide or is a peptide composition having a peptide portion.

Claim 6. The method of claim 5, wherein said peptide or peptide composition effects LPS-uptake or LPS-stimulated cytokine production.

Claim 7. The method of claim 6, wherein said molecule is a peptide having an amphipathic α-helix that binds to SR-BI/CLA-1.

Claim 8. The method of claim 7, wherein said peptide is composed solely of L-amino acid residues.

Claim 9. The method of claim 7, wherein said peptide is composed solely of D-amino acid residues.

Claim 10. The method of claim 5, wherein said molecule is a peptide composition and wherein said peptide portion of said peptide composition has an amphipathic α-helix that binds to SR-BI/CLA-1.

Claim 11. The method of claim 10, wherein said peptide portion of said peptide composition is composed solely of L-amino acid residues.

Claim 12. The method of claim 10, wherein said peptide portion of said peptide composition is composed solely of D-amino acid residues.

Claim 13. The method of claim 1, wherein said molecule is selected from the group consisting of a cholesterol absorption inhibitor, a viral fusion inhibitor, a negatively charged lipid that binds to CLA-1 with a Kd lower than 10^{-7} M; an anti-SR-BI/CLA-1 antibody, of fragment thereof that binds SR-BI/CLA-1, and a chemical substance that binds to SR-BI/CLA-1 with a Kd lower than 10^{-7} M.

Claim 14. A pharmaceutical composition for the treatment of sepsis, inflammation or infection comprising providing to a recipient a physiologically effective amount of a pharmaceutical composition comprising:

(A) a molecule that targets SR-BI/CLA-1; and

(B) an auxiliary agent, excipient, or uptake facilitating agent.

Claim 15. The pharmaceutical composition of claim 14, wherein said physiologically effective amount is effective for providing a treatment for sepsis.

Claim 16. The pharmaceutical composition of claim 14, wherein said physiologically effective amount is effective for providing a treatment inflammation.

Claim 17. The pharmaceutical composition of claim 14, wherein said physiologically effective amount is effective for providing a treatment infection.

Claim 18. The pharmaceutical composition of claim 14, wherein said molecule is a peptide or is a peptide composition having a peptide portion.

Claim 19. The pharmaceutical composition of claim 18, wherein said peptide or peptide composition effects LPS-uptake or LPS-stimulated cytokine production.

Claim 20. The pharmaceutical composition of claim 18, wherein said molecule is a peptide has an amphipathic α-helix that binds to SR-BI/CLA-1.

Claim 21. The pharmaceutical composition of claim 19, wherein said peptide is composed solely of L-amino acid residues.

Claim 22. The pharmaceutical composition of claim 19, wherein said peptide is composed solely of D-amino acid residues.

Claim 23. The pharmaceutical composition of claim 18, wherein said molecule is a peptide composition and wherein said peptide portion of said peptide composition has an amphipathic α-helix that binds to SR-BI/CLA-1.

Claim 24. The pharmaceutical composition of claim 23, wherein said peptide portion of said peptide composition is composed solely of L-amino acid residues.

Claim 25. The pharmaceutical composition of claim 23, wherein said peptide portion of said peptide composition is composed solely of D-amino acid residues.

Claim 26. The pharmaceutical composition of claim 14, wherein said molecule is selected from the group consisting of a cholesterol absorption inhibitor, a viral fusion inhibitor, a negatively charged lipid that binds to CLA-1 with a Kd lower than 10^{-7} M; an anti-SR-BI/CLA-1 antibody, of fragment thereof that binds SR-BI/CLA-1, and a chemical substance that binds to SR-BI/CLA-1 with a Kd lower than 10^{-7} M.

AMENDED SHEET